REMARKS/ARGUMENTS

Claims 1, 2, 5-7, 9, 11, and 27 are pending in this application. Claims 3, 4, 8, 10, and 12-26 have been previously canceled.

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. This amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

35 U.S.C. §103 Rejections

Claims 1, 2, 5-7, 9, 11, and 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Eury (USPN 5, 443,458) in view of WO 01/07066 (hereinafter "WO '066).

To reject a claim under 35 USC §103(a), the Examiner bears the initial burden of showing an invention to be *prima facie* obvious over the prior art. See *In re Bell*, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1992). If the Examiner cannot establish a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent. See *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed Cir. 1992). The Examiner must meet a three-part test to render a claimed invention *prima facie* obvious.

To begin with, the prior art references cited by the Examiner must provide "motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the application." See *In re Kotzab*, 55 U.S.P.Q.2d 1316 (Fed. Cir. 2000). Where one reference is relied upon by the Examiner, there must be a suggestion or motivation to modify the teachings of that reference. *See id.* Where an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references. See *WMS Gaming Inc. v. International Game Technology*, 51 U.S.P.Q.2d 1386 (Fed. Cir. 1999). The suggestion may be found in implicit or explicit teachings within the references themselves, from the ordinary knowledge of one skilled in the art, or from the nature of the problems to be solved. *See id.*

Second, the prior art references cited by the PTO must suggest to one of ordinary skill in the art that the invention would have a reasonable expectation of success. See *In re Dow Chemical*, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). The expectation of success, like the motivation to combine two prior art references, must come from the prior art, not the applicant's disclosure. *See id.*

Finally, the Examiner must demonstrate that the prior art references, either alone or in combination, teach or suggest each and every limitation of the rejected claims, See *In re Gartside*, 53 U.S.P.Q.2d 1769 (Fed. Cir. 2000).

If any one of these three factors is not met, the PTO has failed to establish a *prima facie* case of obviousness and the applicant is entitled to grant of a patent without making any affirmative showing of non-obviousness.

Eury discloses a stent comprised of a biodegradable multilayered laminated construction wherein one layer represents the stent body and additional layers release drugs. WO '066 discloses PPARδ antagonists for the reduction or prevention of the development of foam cells from macrophages. The inventors of the WO '066 application suggest that drugs with this mechanism of action may also be used for the prevention of restenosis. WO '066 also discloses that a PPARγ agonist, rosiglitazone, inhibits macrophage foam cell formation.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to combine these teachings. As mentioned above, in order to find obviousness there must have been some suggestion or motivation to combine these teachings. There is not such suggestion or motivation present. It should be noted that Eury generally discloses classes of drugs such as drugs which "address restenosis" such as angiopeptin, methotrexate and heparin, anti-coagulants, chemotherapeutic agents, and anti-thrombotics such as heparain and prostacyclin. This broad disclosure does not specifically mention PPARγ agonists, and certainly not rosiglitazone.

As noted above, in combining references, there must be a reasonable expectation of success. The mere fact that Eury generally discloses the class of drugs that "address restenosis" does not mean that Eury has disclosed each and every drug that may affect restenosis regardless of the mechanism of action. Furthermore, Eury's disclosure does not ensure that each and every

drug that addresses restenosis will be effective in delivery from a stent. WO '066 discloses the use of PPARδ antagonists systemically for a variety of disease. There is no expectation that such an agent meant for systemic delivery would be effective for site-specific controlled-release delivery from a stent to prevent restenosis, as is required in the claims under rejection. For example, a systemic agent is metabolized through various mechanisms and systems of the body, most importantly, through the liver. Site-specific delivery to the lining of an artery is local administration which bypasses such mechanisms and systems.

Therefore, since the Examiner has not established a *prima facie* case of obviousness of claims 1, 2, 5-7, 9, 11 and 27 over Eury in view of WO 01/07066, it is respectfully requested that the Examiner withdraw this ground of rejection.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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